UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE No. 2:12-MD-02327
THIS DOCUMENT RELATES TO	:	MDL 2327
GENERAL DEPOSITION RE: TVT	:	JOSEPH R. GOODWIN US DISTRICT JUDGE

- - -

March 13, 2017

- - -

Deposition of JOHN R. WAGNER, M.D., held at Marriott Melville, 1350 Old Walt Whitman Road, Melville, New York, commencing at 9:04 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
Deps@golkow.com

APPEARANCES:

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
BY: BRYAN F. AYLSTOCK, ESQUIRE
17 East Main Street
Suite 200
Pensacola, Florida 32502
850.202.1010
baylstock@awkolaw.com
Representing the Plaintiff

RIKER, DANZIG, SCHERER,
HYLAND, PERRETTI, LLP
BY: MAHA M. KABBASH, ESQUIRE
Headquarters Plaza
One Speedwell Avenue
Morristown, New Jersey 07962-1981
973.538.0800
mkabbash@riker.com
Representing the Defendant

ALSO PRESENT:
Ted J. Tanenbaum, Esq.

- - -

TRANSCRIPT INDEX

- - -

- - -

EXHIBITS

- - -

- - -

EXHIBITS

- - -

Page 42

lower?
MS. KABBASH: Objection to form.
You can answer.
A. Again, I think that it depends on whether the patient needs mesh or not. I think when I think about these terms, I think does this patient need a mesh or not or can she get by with a traditional repair. And then if I decide that yes, she's at high risk for some reason and needs a mesh implant, should I place it vaginally or abdominally has a number of factors.
If I think a patient requires a very large mesh implant of the anterior apical and posterior walls, I would prefer to place that abdominally if she is a candidate for abdominal surgery.
Q. And that's because in your experience, the rate of adverse events is lower abdominally as opposed to transvaginally, correct?
A. In my experience, and as well as, you know, the experience I think of

Page 43

others in the literature and colleagues, by avoiding vaginal incisions, you seem to minimize the risk of complications related to the mesh.
Q. Can you do a -- you mentioned a patient not being a candidate for traditional repair.
Do you still do traditional repair for stress urinary incontinence?
MS. KABBASH: Objection to form.
You can answer.
A. If by traditional you mean a Burch colposuspension or an MMK or a pubovaginal sling or a Pereyra or a Stamey, by and large, no. I think that I used to do a lot Burches and Pereyra's. Those were my procedures of choice, but the TVT product and line of products has really revolutionized that procedure.
Q. Let me just ask you directly.
You still do Burch procedures from time to time, correct?
A. I think I've done one Burch in the last two years or three years.

Page 44

Q. And what other non-mesh procedures can be done for the treatment of SUI?
A. Well, traditionally, we used to do anterior repairs with a Kelly plication. We would do a Burch procedure. For recurrent stress incontinence, we would often do a pubovaginal sling retropubically with either autologous graft or synthetic material. And then you had your needle suspension procedures, like the Pereyra and the Stamey.
Q. You can do a Burch procedure laparoscopically, correct?
A. No, I've never done that.
Q. You haven't seen it done?
A. I've seen it done. I've never done one.
Q. But it's possible, doctors can do them, correct?
A. You can do a Burch procedure laparoscopically or robotic or via an open incision.
Q. Let's move now to your

Page 45

publications on your CV.
How many of these, when you say publications or national presentations, how many articles have you had published in the peer-reviewed medical literature?
A. Four, I think.
Q. Does that include abstracts that were presented via poster at a conference?
A. No.
Q. And then you've had a number of presentations in addition to the peer-reviewed publications, correct?
A. Correct.
Q. Do any of these publications or presentations involve the treatment of stress urinary incontinence?
A. No.
Q. So you've never had a publication or presentation on the treatment of stress urinary incontinence, correct?
A. Not at a national meeting.
Q. And the other ones you've had were as a consultant or a proctor for

Page 86

materials is reflected in Exhibit 3, correct?
A. No. Most of the time we just talked about I reviewed recently.
Q. So that would be in either the invoice that I wasn't provided yet or the e-mail or would be reflected in a future invoice?
A. Or the invoice that I haven't provided her with yet.
Q. Right, okay.
MR. AYLSTOCK: Let me hand you Exhibit 9.
(Exhibit Wagner 9, Gynecare TVT Instructions for Use, was marked for identification, as of this date.)
BY MR. AYLSTOCK:
Q. Do you recognize Exhibit 9, Doctor?
A. I do.
Q. You recognize that as the instructions for use for the TVT Retropubic product, correct?
A. Yes.

Page 87

Q. In your report, you state that you use the instructions for use for educational purposes with your residents, correct?
A. I do.
Q. Why is that?
A. It goes to sort of what you asked me about textbooks. The surgery that we do now is so different than the surgery when I was trained. When I was trained, the operations we were doing had been pretty much unchanged for 80 to a hundred years, and we had atlases and textbooks that reflected those operations. I mean, our suture materials were better. Our operating environments were better. Our surgical techniques were better, but our actual procedures were pretty much unchanged. And in today's world, whether it's vaginal slings, vaginal mesh repairs, whether it's single incision surgery, whether it's robotic surgery, it's really hard to find an up-to-date textbook to describe these things. And by the time

Page 88

you do, it's probably outdated within a couple years.
So, I just found that when I have a new resident or fellow and they have not seen this operation before or they've not handled a particular device before, a stapler, a single incision, I encourage them to take this with them and look at it.
Q. I think you even say you encourage them to take it home and study it, correct?
A. Yes, I do.
Q. And that's because what's in the IFU should be the most up-to-date information known to the company as to the implantation procedure and how to perform it, correct?
A. Again, I have problems with that term "up-to-date."
You know, I think that the IFU reflects the company's obligation to describe their product and to describe adverse potential side effects related to

Page 89

their product. And yes, I mean, you could learn something tomorrow and it might take an IFU a while to catch up.
I don't expect the IFUs to replace surgical judgment or up-to-date surgical management, but I do find it's a very good way to introduce somebody to a product, and that's really what I would use them for. Whether it's TVT or really any other product, to introduce a resident to that product.
And I might say to them look, it says here that you can X, Y or Z, but we found you could even do A, B and C with this too and expand on it. Or I might say it says here you can do this, but some of the recent data says you can't do that.
So again, it's a good stepping stone to get off on teaching somebody how to use a product, is how I would use the IFU.
Q. And you mentioned adverse events are reflected in the IFU, correct?
A. Yes, they are.

Page 94

TVT products even in the absence of doctor error, correct?
A. Yes.
Q. Same question with regard to recurrence of incontinence, correct?
A. Correct.
Q. And same with regard to bleeding, including hemorrhage or hematoma, correct?
A. Correct.
Q. And you would also agree that following the implantation of the TVT family of products, one or more revision or surgeries may be necessary to treat these adverse reactions, correct?
A. Correct.
Q. And that can occur even in the absence of doctor error, correct?
A. Correct.
Q. And you would agree that the TVT mesh -- well, you're aware, Doctor, are you not, that in the TVT family of products they're all the same polypropylene mesh, correct?

Page 95

A. Correct.
Q. And that's Prolene mesh, correct?
A. Correct.
Q. Do you agree that in some cases, that Prolene mesh needs to be removed in whole or in part and significant dissection may be required of the tissue to get to the mesh, correct?
A. Correct.
Q. And that can occur with the TVT products even in the absence of doctor error, correct?
A. Correct.
Q. Have you personally explanted Prolene mesh in your practice?
A. Yes.
Q. How many times?
A. I've explanted Prolene mesh in suburethral slings probably four or five times, but I've explanted mesh in other parts of the vagina in the operating room maybe 20 to 30 times and in the office multiple times.

Page 96

Q. Prolene mesh, correct?
A. Prolene mesh like you'd see with the Prolift system. Typically that was my main product, so it would be primarily the Prolene mesh in the Prolift system.
Q. Okay. Where a patient presents with the need for explantation of the mesh, is that something you normally do personally, or do you refer cases out for treatment sometimes?
A. No, I actually do that personally.
I guess I should tell you too that of the TVTs that I have treated, I think only one of them was mine. The rest -- actually, two of them were mine. The rest were referred to me. So about half of the four or five were referred to me. The other two were mine.
Q. And by "mine" you mean --
A. My patient.
Q. -- you implanted the original TVT device, correct?
A. Yes, I implanted the original

Page 97

TVT device.
And I should say that on one of them it's pretty clear that the patient disrupted the repair 'cause she had sex the next night and disrupted the repair, so I don't think that was the fault of anything other than the patient not adhering to her restrictions.
Q. In the other case, did the patient adhere to the instructions and refrain from sex for the appropriate time?
A. As best as I know, yes.
Q. And she still had suffered an adverse event from the TVT product?
A. She did. She had a small mesh erosion that I had to excise.
Q. And that mesh erosion, I take it, was not caused by your error, correct?
A. Error's a funny word. We do our best to section, we place it where we like to place it. We keep our fingers crossed that we haven't devitalized the tissue so that it heals well, but it can occur without any doctor error. It's an

Page 106

Q. Okay.
A. And I think that as part of that, you need an armorterium [sic], is that the word I'm looking for, of tools.
Q. And one of the tools is the IFU?
A. Is an IFU.
Q. Okay.
A. So I would hold myself out as an expert at teaching in that regard.
Q. Okay. But not with regard to --
A. But not --
Q. -- IFUs specifically, correct?
MS. KABBASH: Objection to form.
A. But not with the industry standards for what goes into the IFUs.
Q. Correct.
Is that correct?
A. Correct.
Q. Okay, thank you.
Now, the instructions for use on the TVT products also have implantation instructions for the physician, correct?
A. Yes.
Q. And similarly, would you agree

Page 107

that with regard to the manner of implantations, it's important that the physicians be told through the IFU the correct manner of implantation of the particular product?
A. I think how a physician learns to do this should not be just by reading the IFU and doing this. I think that if somebody wants to expand their surgical repertoire to anything, they should go to postgraduate courses, be proctored, they should learn -- if I'm understanding the question, the question is can a surgeon just read the IFU and do the surgery, I would say no.
Q. Yeah, that really wasn't my question.
I guess my question relates back to in your report on page 3, you would agree that the IFU should be where the physician -- one of the things that the physician relies upon to look for the correct manner of implantation of the product, correct?

Page 108

A. I think the IFUs provide a nice written summary of standard use of the product.
Q. And because of that, because doctors rely on it, it's important that the IFUs be accurate, correct?
A. I think the IFUs should be accurate, yes.
Q. Because if the IFU's not accurate, a doctor may rely on it and give bad information to a patient or implant it incorrectly or do something else that's wrong, correct?
A. A doctor could implant something incorrectly for a variety of reasons that probably have nothing to do with the IFU.
Q. Well, you agree if the IFU is incorrect to the best manner of implantation, or unclear, that can lead to adverse consequences to the patient, correct?
MS. KABBASH: Objection to form.
A. I would like the IFU to be as clear as possible.

Page 109

Do I expect it to be a perfect document? No more than I expect, necessarily, my textbook chapter to be a perfect document. But in general, they're a good summary of whatever product it is and what the company feels should be part of its use and reactions and warnings and side effects.
Q. Okay. Let's go now to your expert report, Exhibit 6.
Did you write this report?
A. I think that probably two-thirds of this are my dictation and corrections of my dictations. Clearly these reflect my opinions, but in terms of organizing this, I clearly had help from counsel. They helped me organize sections. But most of this is dictated by me and corrected by me.
Q. You said about two-thirds?
A. About two-thirds is directly from my Dictaphone. The others are paragraphs that I had editorial control over and changed in certain ways, but

Page 118

regard to the Burch procedure, your patients did well, did not suffer an adverse event, correct?
A. They had typical --
MS. KABBASH: Objection.
A. -- Burch outcomes. You know, there were times when it didn't work well. There were times when they had catheters for three or four weeks. There were times when it didn't tighten them enough.
You know, with the Burch it was funny because you didn't have different types of options. It was one procedure. So if somebody had intrinsic sphincter deficiency, we would try to do a really tight Burch. If they just had hypermobility, we wouldn't do a really tight Burch. There was a lot more guesswork with Burches, and there was a lot more involved in recovery and pain and complications.
Q. As far as long-term complications from the Burch other than those individuals who suffered from a

Page 119

recurrence, did you have particular patients that had long-term consequences following the Burch that you can recall?
A. No, but I know I had patients who needed a pubovaginal sling because their incontinence wasn't better. I recall hematomas. We were always worried about bleeding.
Q. Those would be transient conditions, correct?
A. Well, transient for months. Yeah, they didn't -- if they had a Burch when they were 60, they didn't have those conditions when they were 80, but they may linger for a long time.
One thing to also remember about a Burch is that if you did have a hysterectomy, the vessels in that retropubic space were often huge too. So there was a significant risk of bleeding with a dissection. It was a much more invasive operation.
Q. One of the risks that's not associated with the Burch, however, is

Page 120

erosion or extrusion, correct?
A. That is correct.
Q. That's a risk that's unique to the TVT family of products or other mesh involved in SUI?
A. It's absolutely unique to operations other than the Burch. The pubovaginal slings, synthetic material could erode. The Burch did not have erosions.
Q. If we turn to page 4 of your report, you detail your experience with the TVT products. I'm going to focus on the TVT Retropubic product for now.
It looks like you performed about 600 to 800 procedures with the device?
A. Yeah, that's my best recollection. We started doing them around 2000, and it became virtually standard. We used it for every patient. That was really the only device on the market for a while that we used.
Q. I'm not going to mark it because

Page 121

I want to take it back, but I'm handing you a TVT device box.
Do you recognize that?
A. I do. It brings back memories.
Q. All right. So, one of the memories it brings back is that the TVT has the polypropylene mesh, the Prolene mesh we discussed, and it's actually fixed to the instruments, correct?
A. It is, yes.
Q. So the device is not just the mesh, it's the instrumentation and the instructions for use, correct?
A. Yes. And I think the handles were reusable. They were separate.
Q. Okay. But the actual trocars here attached?
A. Yes, they were attached and the handles, if I recall, screwed into the bottom of the metal trocars.
Q. So the trocars weren't reusable, just the handles, correct?
A. Just the handles, yes.
Q. How much were you paid,

Page 130

exactly the original Retropubic that shows any lower complication rate.
Q. But in your experience, you prefer the Exact because you find it to be a superior device than the original Retropubic, correct?
MS. KABBASH: Objection; asked and answered.
You can answer.
A. In my hands, the way I feel my way through the pelvis, I'm more confident placing the Exact. That's my -- that's my best answer.
I don't have any peer-reviewed objective data to tell you that it's better. I feel that I have a better feel for where I'm guiding the trocars with the Exact than I did with the original TVT.
Q. So to you, you feel it's a superior device?
MS. KABBASH: Objection.
BY MR. AYLSTOCK:
Q. The Exact.
A. I just come back to in my hands,

Page 131

when I'm doing it, I feel more confident doing it.
Q. Okay. When is the last time you did an original TVT Retropubic implantation, 2006?
A. No. I think I did one or two recently when I was at a hospital, I can't remember which hospital it was, and all the TVT-Exacts had expired. And so I asked them if I could have the original device and they gave it to me.
Q. Okay.
A. But I haven't seen that package in a long time because they gave it to me unwrapped and everything.
Q. But absent an expiration on the Exact, you don't use the TVT Retropubic device anymore?
A. That's correct.
Q. When you were using the TVT Retropubic device, did you use mechanical-cut or laser-cut, or do you know?
A. I am pretty confident that when

Page 132

I used that, it was virtually all mechanical-cut. I don't recall being familiar with the concept of laser-cut until I used the TVT Secur. So I'm fairly confident that everything I used was mechanical-cut.
Q. Did your sales rep or anybody from Ethicon ever explain to you what the difference was?
A. Not that I recall.
Q. Do you know why Ethicon switched to also creating a laser-cut TVT Retropubic device?
MS. KABBASH: Objection to form.
A. I don't know why.
Q. Did you ever ask them?
A. No, I don't think I ever have. I may have asked my rep when I had the TVT Secur questions about the laser-cut, but until recently, maybe four or five months ago, I actually wasn't aware that you could get the meshes in both ways. That was a relatively new discovery on my part. I think I've always used the

Page 133

mechanical-cut except for the Secur because I think the Secur only came laser-cut.
Q. When you did become aware of the difference, what were you told about why there was a difference?
A. I recall, I think, having that discussion with my GYN clinician in the O.R., possibly when they were reordering, and I remember thinking it didn't make any difference to me. I think I remember saying whatever's cheapest, if there was a difference.
Q. Okay. If you add up all of these Ethicon devices over the years, it looks like you've done 2,000, 2400 such operations involving the TVT family of products.
Is that about right?
A. I think that's probably about right.
Q. Did you ever keep a registry for your patients, given the large number that you did?

Page 146

Q. Not for slings?
A. I haven't used Coloplast for slings, no.
Q. Any other manufacturers -- have you used any other manufacturers' products, mesh products, for the treatment of stress urinary incontinence other than Johnson & Johnson?
A. I've used the Caldera slings a few times.
Q. The Desara?
A. A Caldera I think is the name. It's the preset ones that -- it's put out by a company that basically mimics every sling that's on the market. So the advantage is a hospital can buy the complete set and it sort of mimics the Monarch, it mimics all the TVT products. They have a mimic for everything.
Q. Have you used the AMS products for SUI?
A. No, I don't think I have. If I did, it was just once or twice. I don't really recall. And if I did, it was

Page 147

probably in a cadaver lab setting somewhere. I really don't have any experience with AMS products.
Q. And Boston Scientific slings, same thing?
A. I did not use their slings. I used their Uphold for anterior and apical support.
Q. In those times where you removed mesh from women, TVT, Prolene mesh, did you request any particular analysis of the explanted mesh?
A. No.
Q. Did you personally review the pathology reports for those?
A. I'm sure that I did, and I'm sure that I probably sent it to pathology.
Q. Did you in that request a SEM analysis?
A. No.
Q. Did you request any particular analysis of those explanted meshes?
A. No, I did not.
Q. I take it you're not a

Page 148

pathologist?
A. No.
Q. And don't hold yourself out to be an expert on pathology?
A. No.
Q. Same with you're not an epidemiologist?
A. No, I'm not an epidemiologist.
Q. You're not a biomedical engineer?
A. Not a bit.
Q. And you've never done a comparison study of different mesh designs?
A. No, I have not.
Q. And you don't hold yourself out to be an expert in medical device design?
MS. KABBASH: Objection to form.
A. Not in the bench work of design, but I think I have a handle on what seems to work best for me and for other physicians in the O.R. just based on experience.
Q. But with regard to comparison of

Page 149

different designs, you don't have an expertise on that?
A. Beyond my own surgical experience, no.
Q. And you agree that would be anecdotal experience, correct?
MS. KABBASH: Objection.
BY MR. AYLSTOCK:
Q. I mean, I guess you haven't done a study on SUI. We've established that.
A. No, but the problem I have with anecdotal would mean that there's a total absence of any ergonomic literature suggesting that one handle might be better than another, and I'm not sure I could say that. So I'd say that my migration to certain products over my career probably involves as much how I can handle the device as what data may be out there supporting a superior design or ergonomics that agrees with what I'm feeling.
Q. So it's based upon your clinical experience in treating particular patients, correct?

MS. KABBASH: Objection.
A. Supplemented with what I may be exposed to at the time regarding design advantages, et cetera.
Q. In your opinion, should a medical device company inform physicians about potential complications associated with its medical device?
A. Yes.
Q. And would you agree with me that one of the ways to do that is through the IFU for the medical device?
A. Yes.
Q. If you go to page 5 of your report. There's some information about your payment at the time of a preceptor.
Do you see that?
A. Yes.
Q. And you list, you state that you believe that Ethicon reimbursed you about $50,000 for those -- for that time; is that correct?
A. Yes.
MS. KABBASH: I apologize. What

page are we on?
MR. AYLSTOCK: Page 5.
MS. KABBASH: Thank you.
BY MR. AYLSTOCK:
Q. Have you confirmed that, or is that just your best estimate?
A. That is -- I actually thought that number was less, but apparently I guess working for -- as a proctor or preceptor for many years ago, it did total that amount. That number was actually based on records from Ethicon.
Q. Did you look at those records?
A. No. But I can recall that standard rates for teaching somebody for half-day or a full day were about either $500 for a half-day and a thousand for a full day, and if I acted as a preceptor for a cadaver course, I think there was a higher fee for that. Those were pretty standard rates.
Q. Did they pay for your travel to these courses?
A. They probably would if I asked

them, but I kind of just paid for my own travel.
Q. Did you receive any honoraria from them?
A. I'm probably misunderstanding the question because I thought that's what that was. That five hundred or a thousand, does that not qualify as an honoraria? I don't know. I got paid.
Q. You got paid for it, okay.
And I take it you've also got paid by Wyeth and GlaxoSmithKline and all of those other companies for your work for them, correct?
A. I got flat fees for giving talks. It was pretty much for the medical aspect of that consulting. It wasn't any -- with the exception of Covidien, it wasn't any involved with the company, per se. It was just flat fee. I was on their speaker panels, give talks.
Q. And you're still on various speaker panels and so forth, correct?
A. I don't think so. I think they

outlawed those. At least my hospital did. You can't be on a speaker panel as of about four years ago.
Q. You're still being paid for doing things for medical device and pharmaceutical companies, correct?
A. That is correct.
Q. In addition to what you're doing in this case for Ethicon, correct?
A. Correct.
Q. You mentioned some things you reviewed, and that includes some procedural videos.
Do you see that?
A. You're down at the bottom of that page?
Q. Right in the middle "Materials Reviewed."
A. Yes.
Q. What procedural videos did you review?
A. I had a TVT -- I had several TVT videos -- "video" is a bad term. I'm probably dating myself. Disks. They

Page 162

track record.
Q. Okay. And the TVT Retropubic is a midurethral sling, correct?
A. Correct.
Q. Are the other TVT products also midurethral slings, or are there differences?
A. Yes, they all are.
Q. Do you know whether Dr. Ulmsten's, the type of product Dr. Ulmsten used that then was followed up by Dr. Nilsson was a TVT laser-cut or a TVT mechanical-cut?
A. I always made the assumption it was mechanical-cut. I thought a laser-cut came along later, but I could be wrong on that.
Q. You don't know as you sit here today?
A. I don't know with a hundred percent certainty, no.
Q. And with regard to the studies you referenced that support the TVT Retropubic device, do you know how many of

Page 163

them involved TVT mechanical-cut versus TVT laser-cut?
A. No.
Q. Are you familiar with -- well, I guess you've never actually implanted a TVT laser-cut -- TVT Retropubic laser-cut, to your knowledge, correct?
MS. KABBASH: Objection to form.
A. I actually don't know that. I consider those slings interchangeable. I know I've implanted the mechanical-cut, but as far as I'm aware, I could have easily implanted a laser-cut mesh. It would have been the same to me.
Q. You wouldn't know the difference if you held it?
A. I mean, if I really carefully pulled on it and tugged on it and tried to wreck it, I'd see the difference, but I'm not trying to pull and tug it and wreck it before I put it in. So to me they're interchangeable.
Q. So you don't know the biomechanical properties of each and

Page 164

whether they're the same or different?
MS. KABBASH: Objection to form.
A. To my mind, they're clinically the same.
Q. Do you know whether or not the TVT laser-cut is stiffer mesh than the TVT mechanical-cut?
A. Again, I come back to clinically to me, it makes no difference to me whether it's laser-cut or mechanical-cut.
Q. You say clinically, but you don't know as we sit here today whether you've actually ever implanted a TVT laser-cut retropubic, correct?
MS. KABBASH: Objection to form.
A. That is true. But it's not a characteristic that I would ever insist upon, and so I could have implanted multiple laser-cuts. I'd actually have to check the requisition office in our hospital and in my other hospital to see what they ordered. But I do know that I have used the mechanical-cut mesh.
Q. And the reason you don't know

Page 165

the difference is because Ethicon never explained to you as a doctor implanting 800 TVT Retropubic devices what the reasonable differences are between the laser-cut mesh and the mechanical-cut mesh in the TVT-R, correct?
MS. KABBASH: Objection to form.
A. Actually, that's not exactly true because I had a long discussions with my rep regarding laser-cut with the TVT Secur. So I was actually familiar with the laser-cut and what it looked like. And so, and I also know that if you put excessive force on the mechanical-cut, it looks different than if you put excessive force on the laser-cut. I just don't think that it has any clinical relevance to me as the implanting surgeon on a standard tension-free tape. I'm not putting -- if I'm putting excessive force on that tape and deforming it, then I'm doing it wrong. It's not the tape, it's the doctor.
Q. Okay. So you've observed in

Page 166

your experience with the TVT devices that when you pull on the mechanical-cut mesh, it has more deformation of the pores than if you pull on mechanical-cut mesh, fair?

MS. KABBASH: Bryan, in fairness, I think you misstated a word. You might want to --

MR. AYLSTOCK: I'll try again. Thank you.

MS. KABBASH: You're welcome.

BY MR. AYLSTOCK:

Q. In your prior answer, you had indicated that when you're putting force on the mechanical-cut mesh to a certain extent, it behaves differently than the same amount of force on a laser-cut mesh, correct?

A. Yes.

Q. And can you describe the differences, please, as you've observed in your clinical practice?

A. What I've seen actually is two observations. One is if I'm teaching somebody and they put way too much tension

Page 167

on the mesh, it tends to rope or band maybe and not lie flat. And in that setting, you can also get some irregularity of the edges. And that's clearly a tape that's been inappropriately placed.

The other time that I've noticed the properties of laser-cut versus mechanical-cut is when I'm removing the mesh that I don't like how it's been placed. I found that if I pulled out a laser-cut TVT Secur, that it would maintain its shape a lot better than if I was tugging on mechanical-cut mesh in the process of removing it. I could never really use that mesh again. I'd have to get a new product out of the box because the process of extra tension had deformed it.

But it wasn't -- basically from a properly placed mesh to me, it makes no difference to me whether it's mechanical-cut or laser-cut.

Q. Did you see when that force was

Page 168

applied to the mechanical-cut evidence of fraying of the mesh? Could you see that? Could you see the fraying of the mesh if the mechanical-cut was pulled?

A. You could see irregularity in the mesh. I guess you would call that fraying. I just always thought of it as an irregularity. The edges were jagged if you applied too much tension to it.

Q. Like a barbed wire effect?

MS. KABBASH: Objection.

A. It would have -- it would have -- I would describe not barbed wire. As more like looking at a mountain range, where you have the peaks and valleys of the mountains.

Q. A jagged edge?

A. Yeah, like that.

Q. Now, did you see evidence of particle loss, or particles?

A. Occasionally I would see -- my clamp that I'm using to tug on the mesh for whatever reason could rip the mesh, tear the mesh, there might be a little

Page 169

particle here or there.

Q. You mentioned the need to make sure the mesh was lying flat under the urethra?

A. And without tension.

Q. Why is it important that that mesh be laid flat?

A. I think there's two answers to that question. The first is that it provides a slightly broader base of support rather than a very narrow base of support.

But the other answer to that question, the reason it's important is because if it's not lying like that, somebody's over-tensioning it.

Q. Okay. Now, you agree that when implanting a TVT device, really any of the TVT family of products, but certainly the TVT Retropubic, that it's a blind passage, correct?

A. Yes, it is.

Q. And you as a physician can't visualize that mesh lying under the

Page 178

A. Came in a flat sheet.
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Earlier plaintiff's counsel was asking you about particular articles going through your reliance list and you made a statement something to the effect that "I don't consider any particular article to be authoritative."
Do you remember saying that?
A. Yes.
Q. What did you mean when you said that?
A. That there's no one forever unimpeachable authority really in anything we do in medicine. There's no book chapter. There's no article. There's no opinion piece. There's no authority in medicine that is unimpeachable.
Q. Your expert report on the TVT products cites a lot of medical literature, correct?
A. It does.

Page 179

MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. In stating your opinions or formulating your opinions on TVT Retropubic, did you rely on any one article to the exclusion of others?
A. No.
Q. Were you relying on the body of medical literature that has evolved on TVT slings over time?
A. Yes.
Q. You were asked several questions about a TVT IFU that was marked as Exhibit 9. Can you pull that out? And I think if you turn to page 5 of the IFU that's where are listed several potential adverse reactions that counsel was asking you about.
Is that right?
A. Yes.
Q. And counsel asked you a series of questions about whether certain risks could be caused by TVT and if they could

Page 180

happen in the absence of doctor error.
Do you recall that line of questioning?
A. Yes.
Q. One of the risks that you were asked about was acute or chronic pain.
Do you recall that?
A. Yes.
Q. Is acute or chronic pain a potential risk of any pelvic surgery?
A. Yes.
Q. Is it a potential risk of any surgery to treat SUI irrespective of the use of mesh?
A. Yes.
Q. You were also asked about the potential risk of pain with intercourse that may not resolve.
Do you recall that?
A. I do.
Q. Is that a potential risk of any pelvic surgery?
A. Yes.
Q. Is it a potential risk of any

Page 181

surgery to treat SUI irrespective of the use of mesh?
A. Yes.
Q. In other words, it's a potential risk of SUI surgery that does not use mesh also?
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Correct?
A. Correct.
Q. You were also asked about the potential risk of voiding dysfunction.
Is voiding dysfunction a risk of any pelvic surgery?
A. It's a risk of any pelvic surgery, particularly those that are involved with treating incontinence.
Q. Okay. Is voiding dysfunction a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were also asked about neuromuscular problems or pain.

Page 182

Do you recall that?
A. Yes.
Q. Is neuromuscular problems or pain a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were asked about bleeding including hemorrhage or hematoma.
Do you recall that?
A. Yes.
Q. Is that a potential risk of any surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were asked about the potential risk that repeat surgeries may be required.
Do you recall that?
A. I do.
Q. Is that a potential risk of surgery to treat SUI that does not involve mesh?
A. Yes.
Q. You were also asked about the

Page 183

potential risks of seroma, urge incontinence, frequency and atypical vaginal discharge.
Do you recall that?
A. Yes.
Q. Are all those potential risks of surgery to treat SUI that do not involve mesh?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. You were asked earlier today when was the last TVT Retropubic device that you performed.
Do you recall that?
A. Yes.
Q. You currently use the TVT-Exact; is that right?
A. Correct.
MR. AYLSTOCK: Objection to form.
BY MS. KABBASH:
Q. Is the TVT-Exact similar to the TVT original Retropubic?

Page 184

MR. AYLSTOCK: Objection to form.
A. Yes.
Q. You previously described some of the things that you liked about the TVT-Exact, but is the --
MS. KABBASH: Strike that.
Q. Is the TVT-Exact a retropubic approach to placement of a midurethral sling?
A. Yes.
Q. Are the trocars, though they may be a bit narrower, are they the same shape as the trocars for the TVT Retropubic sling?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. Is the knit of the mesh in the TVT-Exact the same knit as in the TVT Retropubic sling?
A. Yes.
Q. You were asked earlier today about whether you are a biomaterials

Page 185

engineer.
Do you recall that?
A. Yes.
Q. Have you studied, both in your career and in preparing your expert report, how the Prolene mesh in TVT has performed after being implanted in women?
MR. AYLSTOCK: Objection to form.
A. I've watched how it's performed not only in my patients, but also how it's performed through the vast years of medical literature and studies have been done on it.
Q. And is a lot of the medical literature that you have studied in that regard cited in your expert report?
MR. AYLSTOCK: Objection to form.
A. Yes.
Q. How important is the clinical literature, the medical literature as a basis of your opinions about the safety of the use of the TVT implant?

Page 186

MR. AYLSTOCK: Objection to form.
A. How the mesh works in people and how successful it is long-term and the side effects long-term we measure clinically in our reports to me is the best evidence we have for safety and efficacy. We want to know how it actually works in people and we want to know as much as we can about that.
Q. And is that why you've cited that medical literature in your report?
A. Yeah, the medical literature I have in my report includes a tremendous amount of clinical data on real life people having real life mesh placed to treat incontinence over many years.
Q. If you turn to your report's opinion number 2, which is towards the end on page 52.
You have that?
A. I think I do have it.
Q. Opinion 2 says: "The benefits of these products far outweigh their risks

Page 187

in properly selected surgical candidates based on their performance in thousands of women. As reflected in the medical literature as well as my experience, they are not defectively designed."
Do you see that?
A. I do.
Q. With respect to the TVT Retropubic, does that continue to be your opinion?
A. Yes.
Q. And do you hold that opinion to a reasonable degree of medical certainty?
A. Yes.
Q. Is your opinion that the mesh in TVT is not defectively designed based on your review of the medical literature, as well as your experience?
A. Yes, as well as my interaction with colleagues and opinions of surgeons that I respect. It's the entire body of evidence in our urogynecologic community.
Q. If you turn to opinion number 8, which is on the last page of your report.

Page 188

It says: "The possible risks of the TVT family of products are appropriately described in their instructions for use, the patient brochures for the TVT family of products, and in Ethicon's professional education materials."
Do you see that?
A. Yes.
Q. What are the sources of information that --
MS. KABBASH: Well, first of all, strike that.
Q. Do you continue to hold that opinion today?
A. Yes.
Q. Do you hold that opinion to a reasonable degree of medical certainty?
A. Yes.
Q. And on what sources of information do you base that opinion?
A. I base it on pretty much the same thing. I base it on my training, my experience, my interaction teaching residents and fellows, interacting with

Page 189

other urogynecologists, the medical literature, the extent of the medical literature, the quality of the data, and the quality of data that's presented at national meetings and -- that I've attended and read summaries of.
Q. And have you assessed the warnings of adverse reactions section of the TVT IFU in relation to all those sources of information that you just mentioned right now?
A. Yes, I have.
Q. Do you recall if you used the TVT Retropubic, the original, up until the time that TVT-Exact came out on the market?
In other words, I know that you testified that you used TVT Secur, but were there some patients in which you would use TVT Retropubic up until the time that Exact came out on the market?
A. Typically, if they had failed a mini sling, such as the Secur or there was an Adjust, which is another mini sling

Page 194

A. Four or five years, yes.
Q. Okay. Have you ever seen evidence that the mesh in TVT would rope or band in the absence of being overly tensioned by the surgeon?
MR. AYLSTOCK: Objection to form.
A. No.
Q. Mr. Aylstock brought a sample of the TVT device today, and the mesh implant has a sheathe on it, does it not?
A. Yes, it does.
Q. A plastic see-through sheathe?
A. Yes.
Q. What is the purpose of that sheathe?
A. To aid in placement of the sling by minimizing any local trauma that the tape might cause as it's being put in place, and also to minimize any risk of infection.
Q. When you're tensioning the TVT sling, is it your practice to use any kind of instrument in the tensioning process?

Page 195

A. Typically I use a uterine dilator, a number 8 dilator, number 10 dilator, somewhere in that range, but a Hegar dilator to place between the tape and the urethra while I'm tensioning it -- while I'm removing the plastic covers.
Q. And why do you do that?
A. To assure that it's not overly tensioned.
Q. And is that a well-known technique to use some sort of instrument to maximize the proper placement or proper tensioning of the device?
MR. AYLSTOCK: Objection to form.
A. Yeah, people use various instruments just to assure the normal tension -- the proper tension of the sling.
MS. KABBASH: I don't have any more questions.
How much more time does Bryan have?
THE COURT REPORTER: If it's

Page 196

three hours, it's up.
THE WITNESS: He's done.
MS. KABBASH: Go ahead and have a minute because I believe in professional courtesy.
I've been held to a very tough standard by some of your colleagues on this.
MR. AYLSTOCK: No, I understand.
FURTHER EXAMINATION BY MR. AYLSTOCK:
Q. Your opinion 8 in your report about the IFU being properly describing the risks, is that -- are you referring to Exhibit 9 with regard to that report with regard to the risks described?
A. Yes.
Q. And you changed your testimony, or I guess you were asked questions about the type of mesh in your study.
Do you recall those questions?
A. Yes.
Q. And I take it you discussed the type of mesh in that study during break

Page 197

with counsel, correct?
A. I did 'cause she asked me what it looked like, what was the name of it, and I was --
Q. She was the one who suggested to you that it was Prolene Gynemesh PS?
MS. KABBASH: I'm going to object to this line of questioning, but you can go ahead and answer.
Q. Not Prolene, correct?
A. Actually, I remember the Gynemesh PS as being the mesh. That wasn't the issue. My mistake was thinking that that was the same mesh as the TVT. In fact, that mesh is the same as what's in the Prolift in terms of its dime -- pore diameter and things like that.
So, actually it was my error. It wasn't I didn't remember what I put in. It's that I was under the impression that that mesh pore size more reflected the TVT pore size, not the -- but instead it actually reflected the Prolift pore size.
Q. Okay. So you didn't know that